7 Hindu norms on human experimentation

Parsing classical texts

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Introduction

The contemporary requirement that subjects of human experimentation give their informed or free consent to being an experimental subject was first enunciated as a universal norm in the military tribunals after World War Two. The United States brought charges against Karl Brandt, M.D. and 22 others alleging they had committed war crimes by overseeing the Holocaust. In what was to become the Nuremberg Code, Judges Beals, Sebring and Crawford ruled that

All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

1. The voluntary consent of the human subject is essential¹

The Nuremberg Code, although pronounced as self-evident norms that already existed in the natural legal order, was not only not understood to be principles of international law, it was almost immediately widely seen as far too stringent to be of any use.² That being said, in 1966, after 18 years of negotiation, the United Nations put up for signature the two covenants that would define the international human rights regime, the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights.³ Article 7 of the ICCPR states, in its entirety, simply that

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.⁴

In 1976, the ICCPR came into force, and within a few years was understood to enunciate universal principles of international law.⁵ That meant that not

only were signatories bound by the ICCPR, including India, but even non-signatory states were by application of the principle of universality.⁶

Bioethicists in the global environment seek to understand whether norms such as this can be justified in, or supported by, the various religious traditions since the international human rights regime can be seen as secular, Eurocentric and echoing colonial sentiments.⁷ In comparing religions as sources of relevant norms, Hinduism is often queried. Although this query appears on its face to make sense, scholars of subcontinent traditions generally agree that Hinduism is not a religion in the sense of having either a central doctrine or a central authority.⁸ It has neither. Prior to colonial influences, the word referred to the peoples of the subcontinent.⁹ Colonial institutions and authorities, for various political and economic reasons, used their notions of religion to order those peoples, in the process creating religion as a form of self-identity with political features in the late eighteenth and nineteenth centuries.¹⁰ Hinduism came to be distinguished in the colonial context, more or less, from [the religion of] Islam. One of the distinguishing features of this new colonial Hinduism was its foundation in Vedic and related ancient or classical Sanskrit texts.¹¹

I argue later that because bioethics is a function of the political order, only one class of ancient texts, those addressing political order/theory, can be potential justifications of or support for norms regarding bioethics. The central text of this textual tradition is Kautilya's *Arthashastra*.¹² This text purports to give a king comprehensive advice about all aspects of administering a kingdom. It is decidedly secular, treating those we might identify as the religious, including monks and renunciates, at best as potential spies and operatives, or treating religiosity as a good cover for them. Religion, to the extent it is recognized in the text, is entirely instrumentalized for the secular order. However, there is a textual basis for the kingdom's interest in maintaining public health, and doctors of both men and horses are also recognized as having a special status.

There are two ways the original query can be addressed in this context. One, the *Arthashastra* can be projected onto the Constitution of India. Like the ideal kingdom described in the *Arthashastra*, India is established by its constitution as a secular state. In that analysis, being a citizen of India would be read as the central case of what it means to be a Hindu,¹³ and the Constitution would be read as the fundamental source of bioethical norms. That would focus the query, for example, on the fundamental rights defined in the Constitution, including the rights of equality (Arts 14), freedom of speech (Art 19) and freedom of religion (Art 25) and the obligations of the state for the improvement of public health (Art 47). This would require complex analysis and comparison of the *Arthashastra* and the Indian state, an important project but beyond the remit of this paper. Two, the analysis

could more simply examine whether the *Arthashastra* has any norms that could directly be applied to issues related to human experimentation. I will take this approach.

India presents complexity when considering human experimentation and consent. It is in the process of modernizing and has one foot in the past and one in the future. The upper strata of the middle class and above are more heavily influenced by global trends, while the rest of society lives in conditions more continuous with the less affluent India of the 1970s and earlier. The global trend would suggest that norms of autonomy would dictate individual consent is central to medical or scientific interventions of any kind.¹⁴ On the other hand, large and powerful pharmaceutical companies seek to utilize entire populations without significant regard for individual consent.¹⁵ So, for the more affluent, consent in human experimentation presents the same kind of problem it does in the West, but the less affluent subjects of human experimentation face a different set of problems because those citizens rely more heavily on the state for protection from the private sector.

Seeking bioethical norms in the classical Sanskrit texts

The classical Sanskrit literature of India describes several ways to categorize human existence.¹⁶ There are four stages (Skt. *chaturashramas*) that are loosely age-based: *brahmacharya* (student), *grihastha* (householder), *vanaprastha* (retired) and *sannyasa* (renunciation). There are four goals of the human life (*puruṣārtha*): *artha* (socio-economic position); *kama* (fulfilling desired); *dharma* (being virtuous) and *moksha* (liberation). There are four classes (*varṇas*) of human beings: *brahmins* (priests); *Kshatriyas* (rulers); *vaishyas* (merchants) and *Shudras* (labourers).

The canonical Sanskrit texts that can be evaluated as potential sources of bioethical norms are clearly divided into four categories, one for each of the four goals of human life.¹⁷ This makes sense as the different stages/purposes of life are defined by different normative systems or *dharmas*.

First, consider the four stages of life. The first stage, *brahmacharya* (student), prepares one for the following *grihastha* (householder) stage. Once that stage is finished, one enters the *vanaprastha* (retired) stage in which one prepares for the final *sannyasa* (renunciate) stage. Thus, there are two main ways of being in human life. One prepares for and then exists as a householder, and then one prepares for and becomes a renunciate.

Each of these major ways of being (i.e. stages of life) is characterized by certain purposes. The householder is concerned with material and physical well-being, with marriage, children and career (*artha* and *kama*) and with leading a righteous law-abiding life (*dharma*). For this, there are rules contained in the canonical texts known as *sutras* and *shastras*. Accordingly, there

are texts collected under the rubric of *kama*,¹⁸ under the rubric of *artha*¹⁹ and under the rubric of *dharma*.²⁰ Under the *dharma* of being a householder also fall some of the much earlier *Vedic Samhitas*, especially the *Rigveda*, *Yajurveda* and *Samaveda*. These texts cover reciting hymns (*Rigveda*), performing sacrifices (*Yajurveda*) and chanting songs (*Samaveda*), that is, recitations, ceremonies and rituals for many aspects of day-to-day life that focus on being a good householder and are overseen by *Vedic (Brahmin)* priests. The *Vedic* ordering of society fostered a complex legacy of both compassion and tolerance for and towards the other, a sense of fundamental identity with the other, as well as intense inequities, such as the caste system. These legacies were formative in all of the Subcontinent traditions and probably reflected the norms of communal life that formed the earliest communities. The legacies of the *Vedic* order were influential in the Jain, Buddhist, Moslem and other traditions although in Jainism and Buddhism, there were canonical rejections of some of the inequities (such as the caste system).

The main purpose of renunciation, of *moksha* (liberation), is contained in a great wealth of other canonical texts, starting with the final layers of the *Vedas* known as the *Upanishads*.²¹ The *Upanishads* are grouped with two other texts, the *Brahma Sutras*²² and *Bhagavad Gita*,²³ and are said to make up the teachings of *Vedanta*, or the completion or fulfilment of the *Vedas*.²⁴ These texts focus on the state of *moksha*. *Moksha* is obtained or attained after long years spent in seclusion meditating. Moving towards *moksha* after the purposes of life as a householder have been fulfilled, which is the natural progression of a fully lived life, first means separating from the family. This increasing separation is the *vanaprastha* stage that precedes life as a *sannyasin* or renunciate that has attained *moksha*. Although connected to a human body, the *sannyasin* experiences his/her self (i.e. *atman*, pure consciousness) as completely free, and for the more advanced experiences, their *atman* as being one with *Brahman* (the source of consciousness). This state of being is discussed using abstract concepts, including *dharma*, *karma*, *samsara*, *guru*, *atman* and *Brahman*. A central tenet is that direct knowledge (*samadhi*) of these abstract concepts is possible through *sadhana* (meditation).

The *moksha* state of being is profoundly disconnected from and finds no meaning in the political order or any aspect of the *brahmacharya*, *grihastha* or *vanaprastha* stages of life. These beings are even said to exist without ethics or morals, in the sense that there is no need for them to consider what is right since everything they do is in accord with nature and the true Self and cannot be unethical. They are not ethical beings, as they are completely liberated. It is a very refined, rarified and subtle state of being. These beings live not according to *artha-kama-dharma* but according to *moksha dharma*.²⁵ The perfect man is no longer bound by humankind's ethics, laws

or order (*dharma*).²⁶ In Aristotle's formulation in the *Politics*, they would be gods since they are no longer political animals.²⁷

To summarize, there is a difference between life as a householder (*grihasta*) and life as a renunciate (*sannyasa*). These are two centres of gravity, each with its own *dharma*. The renunciate lives apart from society at large and is directly familiar with the abstract concepts that order existence. The householder is embedded in the political/economic order and is not expected to have direct knowledge of the abstract concepts.

The householder could be said to be religious to the extent he follows the ritual norms laid down in the Vedas, but Hinduism cannot be restricted to that set of norms. Since Jainism, Buddhism and Sikhism are all Hindu, and they reject Vedic norms, then whatever a Hindu is, he is not necessarily in the Vedic spirit. The presence of the entirely secular political theory of the *Arthashastra* complicates matters even more. If Hinduism is linked to the Vedic and subsequent classical Sanskrit tradition, including Jainism, Buddhism and secularism, there is no common thing that can be identified as Hindu religion.

Because ethics is a property of political/legal order, I argue that in Hinduism, bioethics is proper for the householder, but not the renunciate and that the abstract concepts (i.e. *karma* and *atman*) are inapt in bioethical analyses.²⁸ Therefore, we would search the *kama*, *artha* and *dharma* texts for norms that could apply to today's bioethical problems. Of these textual traditions, only one concerns itself with systematic theories of political/legal order (i.e. *dharma*), represented best by the *Arthashastra* of Kautilya.²⁹ It presents a thoroughly secular, intensely practical manual for a king, generalized to an ideal kingdom. In that kingdom, the king freely uses all of the institutions surrounding *moksha dharma* for political purposes. There is no concern for the concepts of *karma*, *atman*, *Brahman*, *moksha*, etc., except that the king's spies and operatives can pretend to be of this class of people to infiltrate groups and otherwise work for the maintenance of political and economic order. The king is concerned with his own pleasure and the kingdom's political and economic stability. Much of the book is concerned with maintaining order at the borders of the kingdom, with war and the maintenance of order in far-flung regions. There is a fairly well-developed idea of public order that includes the maintenance of public health, and doctors are recognized as an important part of society, to the extent they can be used as spies at times, and spies can pretend to be doctors for their covert purposes.

Contemporary consent issues in human experimentation

There are three central issues raised by human experimentation today. The first centres on the requirement for human subjects to give consent to being

experimented upon. A second recognizes that the central ethical calculus of human experimentation is sacrifice. The third explores ethical issues regarding the financial consequences of human experimentation.

Consent

Informed, free or voluntary consent is universally recognized as a right of human subjects. The right is based on fundamental notions of autonomy, of the right to self-direct. It is much discussed and, at this point, somewhat unremarkable as an individual right. However, human experiments are not done on individuals because the goal of a human experiment is a statistical picture of the experimental intervention. In developing the statistical picture, the individuality of the subject cannot be considered, only the clinical effects of the intervention. The individual subject disappears into the statistical cohort. This means that a key ethical entity is the cohort of experimental subjects, not any of them individually. In this context, the two ultimate purposes of human experimentation, advances in knowledge and profits, give rise to the two other central ethical problems.

Sacrifice

It is well understood that human experimentation for the development of drugs, devices and treatments is grounded in the civil need for sacrifice.³⁰ Sacrifice is understood to be for both the community and science.³¹ The Belmont Report, one of the foundational ethical documents in the area of human experimentation, makes this clear regarding science in its discussion of the ethical principle of beneficence:

In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.³²

Pope Pius XII, at the very beginning of the radical increase in the authority of science and the production of drugs, in reflecting on the Nuremberg Medical Case, recognizes that the community has a claim on the individual to participate in experimentation for the benefit of the individual, the community and science. However, it must be subject to proper understanding and limits.³³ Not only must the experiments be serious, honest and promote the practice of medicine, but the state must also approve them. Private approval is ethically unacceptable because of the nature of the community. The community is not a whole made up of parts; rather, each element of

the state participates fully in the essence of the state. If the state permitted the private sector to conduct research willy-nilly, it would be abrogating its responsibility to protect the individual.

It must be noted that, in his personal being, man is not finally ordered to usefulness to society. On the contrary, the community exists for man.³⁴

However, there is yet another theory of Lockean implicit consent, in which a state made up of individuals has agreed to a certain kind of unity or governance. Locke developed the idea of tacit or implied consent to justify acts of the government, among other things, those for the benefit of the citizenry.³⁵ Thus, the argument can be made that the polity, acting through its representative government, has approved the willing sacrifice of individuals for scientific knowledge for the good of the community and the individual. Pope Pius XII argues that this is the kind of sacrifice that is misguided.

Profits

The central case of human experimentation is as follows. Researchers for pharmaceutical companies develop chemical compounds that could be used to treat diseases. These compounds begin life as trade secrets, and at some point, if they have promise, they are patented. A patent is a legal monopoly on the compound. Having a patent is not enough to be able to market a compound, however. Before a compound can be marketed, the pharmaceutical company must prove, according to certain standards, to the drug regulatory agencies that the compound is relatively safe if used a certain way and relatively effective for the condition being treated. If the proof is sufficient, the agency may permit the company to market the compound for the intended use. If the agency approves the compound for marketing, it requires the company to label the compound to inform doctors and patients of the identity of the disease it treats and the nature, risks and benefits of the compound. Once labelled, the compound has legal status as a drug. The exclusive approval to market the drug combined with the patent gives the pharmaceutical company complete control over the market for the drug for the patent period.

Although the costs of developing a drug are unknown, closely guarded trade secrets, the drug companies allege they are astronomical. One study reported that the average cost is \$2.7 billion.³⁶ A more nuanced and transparent study reported that the median cost of bringing a single cancer drug to market is \$648 million, and the median revenue is \$1.7 billion.³⁷ Some drugs have star status, blockbuster drugs. These generate at least \$1 billion a year for the owner. Although very few drugs become blockbusters,

their potential drives the industry. Total worldwide pharmaceutical sector revenues were more than \$1.1 trillion in 2017, making it in the top 2 or 3 economic sectors globally.³⁸ Profit margins are in the 25%–30% range, making total global profits in the pharmaceutical sector over \$250 billion.

More than any other industry, the pharmaceutical sector is highly dependent on its research and development segment. . . . Because of the steady loss of patent protection, the invention of new drugs is of vital importance for the pharmaceutical industry. Revenue losses due to patent expiry often are very significant.³⁹

The foregoing detail is warranted to understand the importance of two kinds of people or roles in the pharmaceutical industry, physicians and subjects, both somewhat invisible in the earlier description.

Physicians are required because they are the gatekeepers to the drugs through their prescription writing authority. Sales of prescription drugs “by far” account for most industry revenues.⁴⁰ Industry advertises directly either to physicians or to consumers with the directive to ask their physician for the drug. In 2016, pharmaceutical advertising in the United States alone was ~\$30 billion, about \$20 billion to physicians and \$9 billion to consumers.⁴¹ On gross revenues in the United States of about \$446 billion (2016)⁴² that is about 7%.

The human experimental subject is the other role of paramount importance. Without subjects, no drug could ever enter the market. Subjects are essential in developing knowledge of safety and efficacy, the necessary ingredient in drug⁴³ research and development (R&D). In 2016, industry spent \$60 billion on R&D, or about 14% of revenues.⁴⁴

Although doctors get some financial benefit from the money spent by industry to woo them,⁴⁵ subjects get virtually none. It is this fact, I want to use as the entry point into using sacrifice as an ethical model to understand human experimentation. Subjects can be looked at from two perspectives. On the one hand, they are considered individuals, human beings with dignity, who volunteer to be experimented on. On the other hand, the individuality of the subject is not relevant, rather the value/data from the individual is merged with that from other subjects to become the statistical whole, and statistical knowledge of the cohort is what has value. The ethical relationship between the pharmaceutical company and the subject ends when the raw data have been taken from the subject. Statistical knowledge of the whole is a new ethical entity in the existing system that privileges the creation of private property from the experiment.

After the development of a promising compound, the pharmaceutical company must research its safety and efficacy. Knowledge of safety

and efficacy must be to standards set by the regulatory industry. Since the United States is one of the most important and largest markets for drugs (45% of the global market),⁴⁶ the standards set by its regulatory agency, the U.S. Food & Drug Administration (FDA), are considered exemplary.

The FDA requires quantitative, that is, statistical, measures derived from randomized controlled trials (experiments) to evaluate safety and efficacy. Drug companies design protocols that establish the parameters of the experiments, which must be conducted on human beings. Generally, the FDA must approve experiments in which the data and statistics will be used in an application-seeking market approval. For each potential drug/disease, the FDA and company agree on the number of experimental subjects that the experiments must conduct.

Recruitment of subjects is an area fraught with ethical problems, such as payments received by treating physicians for successful referrals, the therapeutic misconception and others. However, the legal principles that transform a person with a full set of rights into a subject with no rights regarding the researchers are the operative acts establishing the possibility of the sacrifice.

When a person agrees to participate in an experiment, he or she must consent to be a participant. The consent document, by law, is supposed to fully inform the potential subject of the risks and benefits of the experimental intervention. In a standard legal transaction, the informed consent document would have the force of a contract.⁴⁷ A contract would, typically, provide a quid quo pro for things given or received, and, finally, a contract would be the basis for a cause of action in the event there were damages to person or things caused by one of the parties to the contract.⁴⁸ In fact, the informed consent document does none of these things. It is not construed by courts to be a contract;⁴⁹ it provides, if anything, for only a nominal payment for participation,⁵⁰ and it provides no cause of action in the event of an injury.⁵¹

The sacrifice can be described in the terms set forth earlier. A sacrifice is the killing or destruction of something of value to influence the future.⁵² The influence on the future, on nature, occurs through the mediation of the god or other authority in charge of the future who is the intended recipient of the value. That is, the sacrificer takes value from a thing (usually a living thing) by destroying it, transforms it into something invisible and transfers it to the authority to enhance the position of the intended beneficiary of the sacrifice (which does not have to be the sacrificer).

In a scientific experiment, a human being is transformed into an experimental subject. The value of the subject is a kind of biological machine into which an intervention is introduced. Information from the subject is then used to measure the intervention. The humanity of the subject was

abandoned regarding the process when the informed consent was signed. The being on which the experiment is being performed is not fully human anymore, concerning the process.

This is a sacrifice in three senses, or it could be said there are three sacrificers and two sacrifices. In one sense, individuals sacrifice themselves and their rights for one of two purposes: to help themselves or help others. In most cases, the first reason cannot be true because it results from the therapeutic misconception, in which potential subjects are mistakenly convinced the experimental treatment will benefit them.⁵³ The second reason is not valid because none of the research benefits will be freely available to the public except the drug if the experiment can be made successful, and then the public is charged an often obscene amount of money for the drug.⁵⁴ The only advancement of science from drug research occurs within the silos of the individual drug companies. The god is science and truth, neither of which exists in the sacrificial space, and thus the sacrifice for better health and scientific knowledge must usually fail.

In the second sense, the drug company sacrifices the individuals who “consent” to participate. The company strips value from them, aggregates and then monetizes it for itself. The god is the neoliberal economic system that awards greed, and the sacrifice usually works.

In the third sense, the U.S. government has established and maintains the legal and institutional arrangements that support the neoliberal values that encourage individuals to sacrifice themselves out of ignorance and the pharmaceutical companies to sacrifice individuals for their profits. That is, the U.S. government offers its citizens up for sacrifice by the companies. Its sacrifices fail to the extent citizens are not protected and succeed to the extent the large pharmaceutical companies reap extraordinary profits.

If the purity of the sacrificial or ritual space is considered, another set of interesting issues arise. In both cases, the sacrificial space is impure since the individual participates out of ignorance and selfishness, and the company misleads the sacrificial subjects to get them to participate. Why does the sacrifice generally fail for the individual and succeed for the company? One reason could be that the individual does not have the power to influence the gods to which his or her sacrifice is directed, truth and science. A related or underlying question must query whether the individual has a duty to look into the true nature of the sacrifice, whether it is, in fact, possible for there to be a therapeutic benefit or whether the information from the experiment would ever become part of the public domain. The negative answer to these queries is readily available on the internet, but most regular people do not have enough experience and background knowledge to know they can ask those questions, and the authority of the system keeps them in ignorance. They are taught to trust science and scientists. If the potential

subject learned the truth, it would seem there would be no motivation to participate. This explains why there is a cloak of ignorance spread in the general population about the benefits and nature of human experimentation.

But the lesson from the success of the drug company is that the ignorance of the sacrificed thing is no bar to the value being conveyed to the god of the neoliberal system, who can then confer its rewards, profits to the company. This would be consistent with the sacrifice of non-human animals and inanimate things. The status of their consciousness is irrelevant to their value to the god.

Consent and sacrifice in the *Arthasastra*

Sacrifice in the Vedas

The *Arthasastra* was written in the milieu of the *Vedas*. Although it is difficult to date the Vedic texts with any accuracy, it is not unreasonable to say the core *Vedic* texts were relatively complete by about 1,500 BCE.⁵⁵ They underlay what developed into the *dharma sastric* tradition, a very legalistic system in which the dharma, or heavenly order governing day-to-day life, was controlled by the Brahmanical priestly class.⁵⁶ Sacrifice is central to the *Vedic* texts to insure dharma is maintained in the relations between the non-human and human realms. For the most part, it was controlled by the priestly class, but individuals could also perform some rituals. By the time the *Arthasastra* was written or compiled (c 50–125 CE),⁵⁷ Vedic traditions had crystallized into an oppressive system of laws and rules controlled by the priesthood that governed all aspects of householder life.⁵⁸ The legalism caused widespread counter-movements, including the formation of Jainism and Buddhism and the developments in the theory of government reflected in the *Arthasastra*. The political theory became secular and pluralistic and instrumentalized the Vedic legalism for political ends.

That being said, sacrifice is mentioned throughout the *Arthasastra*, and the tradition of sacrifice it principally refers to is that practised by the *Brahmin* priests based in *Vedic* texts. To understand sacrifice in the Vedas, it is necessary to be aware of their texts and layers.⁵⁹

There are four *Vedas*: the *Rig Veda*, the *Sama Veda*, the *Yajur Veda* and the *Atharva Veda*. The *Rig Veda* contains hymns (chants, mantras) primarily to various deities; the *Sama Veda* contains excerpts from the *Rig Veda*; the *Yajur Veda* contains, in addition to *Rig Veda* hymns, sacrificial prayers or formulas and the *Atharva Veda* consists of a special class of texts dealing with spells, incantations and kingly duties as well as exalted spiritual truths.

Each Veda has two sections. The *Mantra* is the collection of hymns used in the sacrifices, and the *Brahmana* contains the accessories, rules and

regulations for the sacrifices and discloses the meaning of the mantras, which otherwise might remain obscure. Vedic sacrifice was an extremely important way people communed with the gods (deities, higher powers). The sacrifices are “offerings of oblations for the propitiation of the deities.”⁶⁰

Two additional layers of the *Vedas*, developments within the *Brahmana* according to Nikhilananda, are the *Aranyakas* and the *Upanishads*. The *Aranyaka*, or “forest-treatise,” was aimed at the person in the third stage of life, *vanaprastha*. This person has become a hermit and is living apart as he prepares for *moksha* (liberation) and the *sannyasin* stage. Since the sacrifices required and described in the other parts of the *Veda* are too expensive and impractical for the hermit, the *Aranyaka* “prescribes symbolic worship and describes various meditations” that are used as substitutes for the sacrifices. Worship is transformed to the mental level from the physical. The *Upanishads* are the most recent layer of the *Vedas* and describe the abstract principles that are characteristic of the liberated person. Sacrifice per se is not necessary for the *sannyasin* since his obligations have all been subsumed in his inner attainment or perfection.

Consent and sacrifice in the Arthashastra

The text of the *Arthashastra* contains many examples of rules governing day-to-day life such as litigation, family law matters, inheritance, criminal behaviour, property, boundaries, debt, slaves and labourers, commercial transactions and gambling.⁶¹ Topic 24, Organization of Revenue Collection by the Collector, covers all the myriad ways a government raises money, including, for example, from taxes, fines, duties and it covers such topics as standardizations of weights and measures.⁶²

It is clear from the text that physicians play an important role and that there is a system of drugs, pharmacies and pharmaceutical companies regulated for safety and honesty.⁶³ Although it is exactly the same form as it is today, there is a fundamental difference between *Ayurveda* and scientific medicine that radically changes the context and makes the notion of experiment much less likely to occur in the same way. *Ayurveda* is a revealed set of doctrines, like Chinese medicine and homoeopathy, and investigation of substances occurs through a process of Aristotelian *epagoge*, in which reasoning begins with first principles and, for example, the medicinal powers of substances would be described and tested under the framework of the first principles.⁶⁴ The first principles are never questioned. There would be no inductive epistemological activity in the ways understood in a contemporary drug investigation.

I describe the polity because it is only possible to infer the capacity of individuals to consent in the sense of an individual consenting to be

experimented on. Presumably, in this hierarchical society, those with less status have correlatively less capacity to consent, whereas high-status persons would have greater capacity. Would the king require such experiments for public health purposes, he could order people to participate. How he would determine who was chosen is not clear.

However, because sacrifices are such a big part of day-to-day life, and people pay priests and others for the materials and expertise to make sacrifices, sacrifice is a regulated economic and civil activity. We can identify at least one norm in the *Arthasastra* that is more directly applicable to contemporary human experimentation.

In *On Justices*, Chapter 14 deals with commercial subjects, including employment. In that chapter, Topic 66 is titled Partnerships. In Partnerships, the wages and other costs of sacrifice are regulated in some detail.⁶⁵ The rules protect the financial interests of the sacrificers and ensure the sacrifice is completed on behalf of the patron.

It is not a far stretch to analogize the *Vedic* sacrifice to the sacrifices privileged and institutionalized in the neoliberal pharmaceutical sector.

Regarding the sacrifice made by the individual, he or she is both patron and thing being sacrificed. The emphasis of the rule on the sacrifice being completed suggests the state is interested in maintaining the integrity of the sacrificial transaction. Since, on this view, sacrifices are known to work and are such an integral part of day-to-day life, the suggestion is that the institutional misleading of the patron as to the true nature of the sacrifice (it is not therapeutic and it will not result in the common good) would be prohibited. In theory, this is done today with the informed consent process, but it is clear institutional pressures nullify the informed consent generally speaking.

Regarding the sacrifices by the pharmaceutical company and the state, the rules' emphasis on the transactional aspects of the sacrifice suggests that industry would be much more tightly regulated. In other words, the *Arthasastra* envisions a relationship between the state, the citizens and industry that is different from that institutionalized in the neoliberal political order. Here, the state would exercise more control over the financial transactions at the heart of the research enterprise. This could go as far, perhaps, given the centrality of sacrifice to the public, as regulating human experimentation as a utility, setting profit margins and prohibiting or limiting monopolies on medical treatments, devices and drugs. Additionally, it could confer greater power on the individual sacrificers/subjects to negotiate as cohorts for participation or shares in the profits of the drug and set fees, and other benefits subjects could be paid for participation, perhaps based on risk, etc.

About international relations, such as a human rights regime in which the rights of citizens are regulated between kingdoms, it is probably unlikely

under the principles of international relations set out in the *Arthashastra*.⁶⁶ The *Arthashastra* posits a sixfold strategy in international relations. The first principle is the peace pact. If the conditions exist for a peace treaty, then typical issues addressed in the pact would be land, allies, money and projects. This suggests openings for discussion of trade in drugs but recalling the drug trade would not be anything like our trade now, which is already subject to many international, transnational and global agreements. Perhaps, an agricultural compact to grow certain herbs (i.e. drugs) could be envisioned.

Conclusion

The foregoing analysis answers, with a yes, whether Hinduism has any ideas to offer the contemporary regulation/policy of human experimentation. However, that affirmative answer comes only after the question is unpacked and after considerable historical translation of ideas and explanation of the unpacked question. In summary, it seems to envision a more tightly regulated pharmaceutical industry performing experiments on subjects that have been given much more agency.

Whether the norms expressed in the *Arthashastra* can be considered religious is complicated. The centrality of sacrifice to the householder who adheres to *Vedic* norms is indisputable and could be described as religious since, for example, sacrifices are made to deities, etc. Moreover, even in *moksha dharma*, a *dharma* reflected throughout the cultures and traditions of the subcontinent in its more abstract forms, the notion of sacrifice is important, albeit not as a physical rite. However, the *Arthashastra* is decidedly secular and suggests throughout that religion could be used, for example, as a pretence for covert political activity. That suggests the central concern of the rules is to maintain civic order, not to institutionalize a religion.

Notes

- 1 Walter Beals, Harold L. Sebring, and Johnson T. Crawford, "Justices," *Judgement* (August 20, 1947). Trial of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, Vol. 2 ("The Medical Case") (Washington, DC: United States Government Printing Office, 1948), 181–182, www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf, accessed May 20, 2021. There were earlier norms, particularly in Germany, but they cannot be said to have become universal in any sense of the word. Jay Katz, *Experimentation with Human Beings*, 305 (Russell Sage Foundation, 1972), 284–292.
- 2 Jay Katz, "The Nuremberg Code and the Nuremberg Trial: A Reappraisal," *JAMA* 276, no. 20 (1996): 1662–1666, at 1665.
- 3 Samuel Moyn, *The Last Utopia: Human Rights in History* (Cambridge: Belknap Press of Harvard University Press, 2010).

- 4 U.N. General Assembly, *International Covenant on Civil and Political Rights* (December 16, 1966), United Nations, Treaty Series, vol. 999, 171, www.refworld.org/docid/3ae6b3aa0.html, accessed May 18, 2019, Art. 7.
- 5 Moyn, *Utopia*. In the 1950s, the World Medical Association (WMA) and the Council for International Organizations of Medical Sciences (CIOMS) enunciated norms requiring consent, but these norms did not even have the force of soft law at the time. Later, they would become elements of a soft law regarding consent and give content to the ICCPR Art 7 positive law.
- 6 That is, through custom, state practice, *opinio juris*, and other mechanisms, including positive law. Jordan J. Paust, "Customary International Law: Its Nature, Sources and Status as Law of the United States," *Mich. J. Int'l L.* 12 (1990): 59, 59–77. <http://repository.law.umich.edu/mjil/vol12/iss1/2>. See also Roozbeh (Rudy) B. Baker, "Customary International Law in the 21st Century: Old Challenges and New Debates," *European Journal of International Law* 21, no. 1 (2010): 173–204.
- 7 See Makau W. Mutua, "The Ideology of Human Rights," *Virginia Journal of International Law* 36, no. 3 (1996): 589. <https://digitalcommons.law.buffalo.edu/articles/572>. Moreover, in 2019, three of the five seats on the United Nations Security Council are held by states (United States, Russia, and China) that are steadily becoming more nationalistic. Numerous other states, such as Hungary, Poland, the Philippines, and India, are steadily becoming more nationalistic too. This nationalism has acted to severely erode the notion of universal international law, not only in the realm of human rights but also in the more sacrosanct global economic order.
- 8 Peter Das, "Hinduism in Bioethics," *Encyclopedia of Bioethics*, 4th ed., ed. Bruce Jennings (New York: Macmillan Reference USA, 2014), 1523. See also, Peter Das, "On 'Hindu' Bioethics," in *Saṃskṛta-sādhutā: Goodness of Sanskrit. Studies in Honour of Professor Ashok N. Aklujkar*, ed. Chikafumi Watanabe, Michele Desmarais, and Yoshichika Honda (New Delhi, India: D. K. Printworld, 2012).
- 9 But see, Wendy Doniger, *The Hindus: An Alternative History* (Oxford: Oxford University Press, 2010) (noting earlier, but incidental, use of the word "Hindu" in a religious sense).
- 10 See Iza R. Hussin, *The Politics of Islamic Law: Local Elites, Colonial Authority, and the Making of the Muslim State* (Chicago: University of Chicago Press, 2016), 92–95.
- 11 Das, *Hinduism*.
- 12 Kautilya, *Arthashastra: King, Governance and Law in Ancient India*, trans. Patrick Olivelle (New York: Oxford University Press, 2013).
- 13 The explanatory text of Article 25 states that a reference to Hindus includes a reference to Jains, Buddhists and Sikhs. Subsequent Supreme Court cases have recognized this inclusiveness and ambiguity of the word Hindu as referring to a religious affiliation. See Das, *Hinduism*.
- 14 See, e.g., Narges Mahaluxmivala, "Human Subject Protection in India:—Is It Adequate?," *Perspectives in Clinical Research* 1, no. 1 (2010): 15–20.
- 15 Ari Altstedter and Anna Edney, "Culture of 'Bending Rules' in India Challenges U.S. Drug Agency," *The Economic Times* (January 31, 2019), <https://economic-times.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/culture-of-bending-rules-in-india-challenges-u-s-drug-agency/articleshow/67769847.cms>.

- 16 These texts and their norms only applied to the elite Sanskrit speakers and their circles. Doniger, *The Hindus*.
- 17 That is, there are three textual traditions in which texts are drafted and collected under the relevant *purusartha* (purpose), *kama*, *artha* and *dharma*. Wendy Doniger, *Against Dharma: Dissent in the Ancient Indian Sciences of Sex and Politics* (New Haven: Yale University Press, 2018), 1–23.
- 18 See Alain Daniélou, *The Complete Kama Sutra: The First Unabridged Modern Translation of the Classic Indian Text* (1993).
- 19 See Kautilya, *Arthashastra*.
- 20 See Patrick Olivelle (trans.), *The Law Code of Manu (Manava Dharmashastra)* (New York: Oxford University Press, 2004). A central text of the *dharma* tradition.
- 21 Swami Nikhilinanda (trans.), *The Upanishads (With Notes, Explanations and Commentary Based on the Interpretations of Sankaracharya)*, Vol. 4 (New York: Ramakrishna-Vivekananda Centre, 1949–1959).
- 22 George Thibaut, *Vedanta Sutras Parts 1 & 2*, The Sacred Books of the East at Google Books, Vols. 34 and 38, ed. Max Muller (Oxford: Oxford University Press, 1904).
- 23 *The Bhagavad-Gita*, trans. Georg Feuerstein, 2011.
- 24 An additional central text on *moksha dharma* is Patanjali's Yoga Sutras, of which there are numerous translations. See *Yoga-Sutras of Patanjali with the Exposition of Vyasa: A Translation and Commentary*, Vols. 1 and 2, trans. Swami Veda Bharati (India: Himalayan Institute, 1986); Swami Hariharananda Āraṇya, *Yoga philosophy of Patanjali*, trans. P.N. Mukerji (Albany, NY: State University of New York Press, 1983).
- 25 As a *purusartha*, *dharma* means to do the right thing. This is a procedural norm, though, and it does not convey enough information to know what the right thing is. To know substantive right, one has to know the purpose of the norm (*dharma*), and the purpose is inscribed in the other *purusarthas*, *kama*, *artha* and *moksha*, which in turn are active variously during the stages of life. For the householder centre of gravity, or *grihastha ashrama*, the purposes are *kama* and *artha*. To lead a fulfilling life as a householder, one lives according to *kama-artha dharma*. To lead a successful life as a renunciate, the other center of gravity of the stages of life (*sannyasin ashrama*), one must also live according to the *dharma*, but in this case, it is *moksha dharma*. The rules required to achieve liberation or *moksha* are radically different from the rules to live as a householder.
- 26 Nikhilinanda, *Upanishads*, Vol. 2, "Hindu Ethics" section, 1–5.
- 27 Aristotle, *Politics* 1253a28–30, trans. C.D.C. Reeve (Indianapolis, IN: Hackett Publishing Company, 1998), 5.
- 28 That being said, another interesting project would be to examine the *Vedic Samhitas* (mantras and benedictions), *Brahmanas* (commentaries on rituals, ceremonies and sacrifices) and *Aranyakas* (text on rituals, ceremonies, sacrifices and symbolic-sacrifices) for other possible normative guidance. Because the *Upanishadic* texts of the Vedas are clearly concerned with *moksha*, whereas the rest of the Vedas are concerned with the householder's day-to-day life, they would not be part of this project. Would certain rituals/mantras improve certain medical or drug treatments, e.g.? Since amelioration of negative planetary influences is a Vedic subject, would the astrological chart play a role in determining which mantras and rituals would be performed to avoid treatment altogether or ensure its success, etc.? How could that knowledge be used in human experiments?

- 29 See Kautilya, *Arthashastra*. The history of the science of *artha* and Kautilya's *Arthashastra* is intimately bound to the history of the science of *dharma* and *dharma* texts. Doniger, *Against Dharma*, 11–13. The *Arthashastra*, in other words, is about the *dharma* of *artha*.
- 30 See, e.g., Katz, *Experiments*, 176, 291, 731, 735; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, MD: The Commission, 1978). See also, Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," *Daedalus* 98, no. 2 (1969): 219–247.
- 31 See Katz, *Experiments*.
- 32 *Belmont Report*.
- 33 Pope Pius XII, "The Moral Limits of Medical Research and Treatment," in *Proceedings of the First International Congress of Neuropathology*, Acta Apostolicae Sedis 44 (Rome, 1952), 779–787. (Tran. NCWC News Service), as cited in Katz, *Experiment*, 731–733.
- 34 Katz, *Experiment*, 732.
- 35 See John Locke, *Two Treatises of Government*, §2.110, ed. P. Laslett (Cambridge: Cambridge University Press, 1988/1689).
- 36 Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics* 47 (2016): 20–33; Jerry Avorn, "The \$2.6 Billion Pill:—Methodologic and Policy Considerations," *New England Journal of Medicine* 372, no. 20 (2015): 1877–1879.
- 37 Vinsay Prasad and Sham Mailankody, "Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues after Approval," *JAMA Internal Medicine* 177, no. 11 (2017): 1569–1575.
- 38 Matej Mikulic, "Global Pharmaceutical Industry:—Statistics & Facts," *Statista.com* (November 5, 2020), www.statista.com/topics/1764/global-pharmaceutical-industry/, accessed May 12, 2021; Mary Ellen Biery, "The Most Profitable Industries in 2016," *Forbes.com* (August 6, 2016), www.forbes.com/sites/sageworks/2016/08/06/the-most-profitable-industries-in-2016/, accessed May 12, 2021.
- 39 Mikulic, "Global."
- 40 *Ibid.*
- 41 L.M. Schwartz and S. Woloshin, "Medical Marketing in the United States, 1997–2016," *JAMA* 321, no. 1 (2019): 80–96.
- 42 Mikulic, "Global."
- 43 Included are devices and other treatments such as biologicals.
- 44 Mikulic, "Global." However, the pharmaceutical industry does not fund basic research that identifies the promising compounds in the U.S. Basic research is funded by the government, which does not participate in the profits of drugs brought to market. Alexander Zaitchik, "Taxpayers:—Not Big Pharma:—Has Funded the Research Behind Every New Drug since 2010," (Spring 2018), <https://other98.com/taxpayers-fund-pharma-research-development/>, accessed June 3, 2019.
- 45 Schwartz, *Medical Marketing*.
- 46 Mikulic, "Global."
- 47 Valerie Gutmann Koch, "A Private Right of Action for Informed Consent in Research," (April 6, 2014). *Seton Hall Law Review* 45, no. 1 (2015), Chicago-Kent College of Law Research Paper No. 2014–26. Available at SSRN: <https://ssrn.com/abstract=2421065>.

- 48 Koch, "A Private Right," 183–193.
- 49 *Ibid.*
- 50 Moreover, many ethicists consider it wrong to provide more than a nominal fee, if anything, because it would amount to undue influence, which is explicitly prohibited. Christine Grady, "Payment of Clinical Research Subjects," *The Journal of Clinical Investigation* 115, no. 7 (2005): 1681–1687.
- 51 Koch, "Private Right." The federal statute authorizing and regulating human experimentation does not confer an individual cause of action in injured subjects. Rather it authorizes the Office of Human Research Protections to ban or otherwise punish researchers and institutions that cause injuries.
- 52 *Oxford English Dictionary*, 2nd ed. (Oxford: Oxford University Press, 2004), s.v. "Sacrifice," at <https://en.oxforddictionaries.com/definition/sacrifice>. See generally, Henri Hubert and Marcel Mauss, *Sacrifice: Its Nature and Function*, trans. W.D. Halls (Chicago: University of Chicago Press, 1981); René Girard, *Violence and the Sacred*, trans. Patrick Gregory (Baltimore and London: Johns Hopkins University Press, 1979); Walter Burkert, *Homo Necans: The Anthropology of Ancient Greek Sacrificial Ritual and Myth*, trans. Peter Bing (Berkeley: University of California Press, 1983).
- 53 Larry Churchill, "Therapeutic Misconception (T.M.) in Clinical Research," (June 2013), www.mc.vanderbilt.edu/crc/workshop_files/2013-06-21.ppt, accessed July 5, 2019.
- 54 Robert Langreth, "Drug Prices," *Bloomberg* (February 5, 2019), www.bloomberg.com/quicktake/drug-prices, accessed June 5, 2019.
- 55 Nikhilananda, *The Upanishads*, Vol. 1, 7–8.
- 56 See Doninger, *Against Dharma*, 8–13.
- 57 Kautilya, *Arthashastra*, 29. See also Doniger, *Against Dharma*, noting the latest emendations to the text were made in the 4th century C.E.
- 58 See Olivelle, *The Law Code of Manu*.
- 59 The following description is taken from Nikhilananda, *Upanishads*, 2–4. However, these are some of the oldest texts in existence and parts of them are still widely in use in India and among the diaspora, and their complexity cannot be underestimated. For an introduction, see Wikipedia contributors, "Vedas," *Wikipedia: The Free Encyclopedia*, <https://en.wikipedia.org/w/index.php?title=Vedas&oldid=890019870>, accessed May 27, 2019.
- 60 Of note is that human sacrifice can be found in the Vedic texts. See Anonymous, *Truth about Hinduism*, <https://vedkabhed.wordpress.com/2014/02/16/purushamedha-the-human-sacrifice/> (quoting exact citations in the Vedas).
- 61 Kautilya, *Arthashastra*, 179–222.
- 62 *Ibid.*, 109–111.
- 63 There are numerous references under the entries for physicians and medicines in the index of the *Arthashastra*.
- 64 See Dominik Wujastyk (trans.), *The Roots of Ayurveda: Selections from Sanskrit Medical Writings* (India: Penguin Books, 1998), xxx. Francesca Bray, "Chinese Medicine," in *Companion Encyclopedia of the History of Medicine*, Vol. 2, ed. Roy Porter and W.F. Bynum (London and New York: Routledge, 1993), 732–734; Samuel Hahnemann, *Organon of Medicine*, 6th ed. (India: B. Jain Publishers, 1992), Aphorisms 1–29.
- 65 Kautilya, *Arthashastra*, 211–212.
- 66 Kautilya, *Arthashastra*, 277–330, Book Seven: "On the Six-Fold Strategy."